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RECORD OF ORAL HEARING

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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*Ex parte* STEPHEN JOSEPH VESPER

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Appeal 2009-006220
Application No. 09/866,793
Technology Center 1600

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Oral Hearing Held: January 14, 2010

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Before TONI R. SCHEINER, DEMETRA J. MILLS, and
FRANCISCO C. PRATS, Administrative Patent Judges

ON BEHALF OF THE APPELLANTS:

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The above-entitled matter came on for hearing on Thursday, January 14, 2010, commencing at 9:20 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Kevin E. Carr, Notary Public.

THE USHER: Calendar number 46, Appeal number 2009-006220.

Ms. Kornbau.

JUDGE SCHEINER: Thank you. Good morning.

MS. KORNBAU: Good morning. May it please the board, I'm Anne Kornbau, and with me are Laura Scalise and Randall Cherry. We represent the Appellant, Stephen Vesper and the assignee, the United States Environmental Protection Agency.

JUDGE SCHEINER: Before I forget, because I keep forgetting, do you have a business card for our reporter, please?

MS. KORNBAU: Sure.

JUDGE SCHEINER: Thank you.

MS. KORNBAU: This is the first time I've been asked for that at an appeal.

JUDGE SCHEINER: Well, everything is on the record now, so -- well, whenever you're ready.

MS. KORNBAU: I'm sorry?

JUDGE SCHEINER: We're ready whenever you are.

MS. KORNBAU: Okay, thank you. I'm sure you're familiar with the problem of sick building syndrome. This is one of the problems the EPA has been working on solving. It really is often caused by molds that get into the buildings, molds and fungi, which are very difficult to eradicate,

and also to identify. What the inventor here has done has come with -- has found that there are markers that can be used for these organisms, the ones that produce hemolysins. Not all fungi or molds do produce hemolysins. But the ones that do, produce hemolysins that are specific to that particular organism.

So what he has done is -- because animals who are infected with these hemolysins do not produce antibodies to the hemolysins, he's attached antibodies -- labeled antibodies to use -- to check for people who might have been exposed to these hemolysin producing organisms. Also, he can -- if a building has been infected with these organisms, he can take a sample of whatever seems to be the problem, if there's some black mold or whatever, and determine if the building is infected, and if -- with what organism the building has been infected.

The reference that the Examiner is relying upon, Sakaguchi, was published in 1984. And what Sakaguchi was doing was he was checking how the hemolysin went through the body of the mouse. He knew that he had injected hemolysin into the mouse and he was trying to see where it was going, how it would -- which tissues would be infected. Evidently what they were looking for was a way to attack cholesterol that would be less damaging than it -- than the drugs that were already on the market. So, 1984. Yes, there was a hemolysin and antibody assay, but nobody did anything more with it.

It was this particular inventor who discovered that there are these markers for specific organisms that can be used to determine if a person or an animal has been exposed to a specific organism. And it's not the concept of just the immunoassay, because that's well known in the art.

What he has done is found these markers and has made the mark -- has made use of these markers to identify if someone has been affected with -- has been exposed to the organism or if the building is infected with it.

JUDGE SCHEINER: Now isn't this one of the main points of contention in this case, is that the Examiner's position is that you don't have written descriptive support for looking at specific markers, versus any -- a marker of any hemolysin that would detect any mold that produces that enzyme?

MS. KORNBAU: Well, what -- I think the problem here is we don't have the exact language in haec verba. But we do -- I mean, why would you look for specific organisms if they don't produce a hemolysin that's specific to that organism?

JUDGE SCHEINER: Well, isn't that the question? Are you just looking for any, any mold that produces that, or do you -- or was the focus of the invention on determining which specific mold, or which specific organism you were dealing with?

MS. KORNBAU: We were looking for specific organisms. Because I think if we were only looking for organisms producing hemolysins, that's already been done, I mean, for one particular organism that produced a hemolysin.

JUDGE SCHEINER: In other words, in that -- if that were the case, you would just do the agar. You would just do the sheep blood assay.

MS. KORNBAU: Right. But this way, you can predict or you can determine which micro -- which organism you have a problem with. You know, if someone has respiratory problems from a sick building, you can determine -- take a blood sample, saliva sample and determine which

organism has infected that person. Or if the person doesn't show any symptoms, then --

JUDGE SCHEINER: Is that significant for treatment? Do you need to know specifically which organism you have? I mean, is that discussed anywhere in the --

MS. KORNBAU: It's -- because you have to design the treatment, or treating the building, which organisms are infecting the building. Some of them cannot be killed. You just have to take it all down. But if there's one that can be dealt with, say by spraying chlorine on it, it's a lot better than taking down the building.

JUDGE SCHEINER: Okay. Well, why don't we focus on each rejection as -- let's take them in turn and --

MS. KORNBAU: Okay. Well, I think with Sakaguchi, the 103 rejection, this was done in 1984. He knew that he was infecting the mouse, and what he was doing was tracking the progress of the hemolysin through the mouse's organs. We don't know if someone has been exposed to an organism like this. So we can check to see if -- does this person have an allergy, or is it really exposure to a particular organism that's causing the respiratory problems, for example. The fact that Sakaguchi did it in '84 and no one has come up with these markers for these organisms would lead me to believe that maybe there is something unobvious here. There is also an exclusive license on this application, so obviously it has commercial value.

JUDGE SCHEINER: So then the next -- we have -- let's see. We have the -- all right. Now it's our understanding that your position on the 103 then is that Sakaguchi knew that the animal had been exposed, and therefore you don't have an unknown?

MS. KORNBAU: Well, he --

JUDGE SCHEINER: Or an animal of unknown -- or a building of unknown status.

MS. KORNBAU: Right.

JUDGE SCHEINER: So then we also have a -- isn't there a 102 for --

JUDGE PRATS: I believe there is a 102 over claim 33.

JUDGE SCHEINER: There are a lot of rejections in this case so --

MS. KORNBAU: I know.

JUDGE SCHEINER: Trying to figure out the best way to go through them, step-wise.

MS. KORNBAU: Well, again, a method for determining if an animal has been exposed. And I think this where the preamble of the claim puts limitations into it. We're not just assaying for hemolysin. What we're doing is we are determining if an animal has been exposed to one of these organisms.

JUDGE PRATS: So you're saying essentially that the preamble of the claims requires the subject to be an unknown.

MS. KORNBAU: Right, because we're determining if. Whereas Sakaguchi knew that the animal had been injected with the hemolysin.

JUDGE PRATS: Right. But arguably one of ordinary -- wouldn't one of ordinary skill in the art reading Sakaguchi recognize that, "Hey, I can tell if somebody's been exposed to this by assaying for the hemolysin."

MS. KORNBAU: Why did nobody do it for 20 years? I mean, people have been concerned about the mold in the buildings and the exposure to mold for long time. And also, Sakaguchi only used that one hemolysin. Vesper, Doctor Vesper has discovered that there are -- not all fungi produce hemolysins. But the ones that do, the hemolysins are specific. And in his Declaration that was filed in I believe 2005 he showed how very, very simple it is to extract the hemolysin from a number of different organisms.

JUDGE PRATS: Right. But with respect to Sakaguchi isn't that -- I mean, the hemolysin there meets the requirement that it's species specific, correct?

MS. KORNBAU: We didn't know that, because he knew that he had the Aspergillus and he had the hemolysin for that. There's nothing in Sakaguchi that even suggests that this can be used for different types of organisms. I mean, there's a big difference between knowingly injecting the stuff and tracking it through the tissues, from knowing that there are lots of these organisms that produce hemolysins and one can detect them. The animals do not produce antibodies to hemolysins so you can't just do a standard immunoassay. You have to -- as the inventor has, excuse me, pointed out, you have to tag it to an antibody and then --

JUDGE PRATS: Right. But there seems to be a distinction between the 102 and the 103 here, in that you necessarily have to have an unknown. One could argue that, you know, Sakaguchi doesn't have an unknown. But with respect to the 103, you could argue the take home message is that you can assay an unknown for exposure by looking for

hemolysin -- this hemolysin right here, which is inherently species specific, correct?

MS. KORNBAU: We don't know from Sakaguchi that it's species specific.

JUDGE PRATS: But do you need to know that to conduct the assay that's suggested -- that's arguably suggested by that reference?

MS. KORNBAU: You need to know that so you know -- because what we're doing to determine if someone's been exposed to such an organism, and because they each have specific hemolysins, one can determine which organism has been infecting the person or the building.

JUDGE PRATS: So you don't think that Sakaguchi suggests that detecting for the ASP hemolysin suggests that you'd be able to detect exposure to a fumigatus then?

MS. KORNBAU: No, because there's nothing in Sakaguchi other than here we injected the mouse with this stuff and we detected it. We -- not so much detected it, but tracked it through the body.

JUDGE PRATS: Thank you.

MS. KORNBAU: You're welcome. Shall we go on to the written description --

JUDGE PRATS: Sure.

JUDGE SCHEINER: Please.

MS. KORNBAU: Okay. again, with species specific, I think the Examiner is looking for the exact words. And we know that you don't have to have the exact words, but someone skilled in the art reading this would say, "Oh, you can detect this, you can detect this, because they have specific hemolysins." I think there was some question about species versus

strains, which is why I'm calling them organisms. Because it turns out that fungi have their own kingdom, so we don't want to get into the classification of these, so I'm calling them organisms. But they are -- the hemolysin is specific for each organism, which is why this test, this marker is so useful and why it has been licensed exclusively by a very large company. It's a very useful test. It's the only test available right now, other than, you know, just the auger. And this way you can find out what you have, and it's reasonably inexpensive and rapid.

JUDGE MILLS: What language did the specification use when it described the organisms? Didn't it use strains?

MS. KORNBAU: It used strains, right. But --

JUDGE MILLS: And how would one of ordinary skill in the art view a strain as compared to a species?

MS. KORNBAU: Well, what --

JUDGE MILLS: And do we have any evidence of record showing that they're the same?

MS. KORNBAU: One of the problems -- I was speaking with the inventor yesterday -- Tuesday. And he said that there is -- with classification, he said there are a lot of interchangeable -- people use the terms interchangeably. And that's why I'm -- for this -- for the purposes of this argument, it's a specific organism. I don't want to get into the species and strains, because the specific organism you're looking for is producing a hemolysin that is specific to that particular organism. And that's -- that's the whole point of the test, that if you have specific hemolysins produced by individual organisms then you can analyze for that hemolysin and say, "Yes, this organism is present, or this organism is not present."

JUDGE SCHEINER: Is there any place in your specification where you -- where the inventors raise antibody against hemolysins from different organisms, strains, species, whatever, and show that they're specific for that molecule?

MS. KORNBAU: Well, you can't raise antibodies to the hemolysins. That's the problem.

JUDGE SCHEINER: No, no, no. I mean, detect them one from the other.

MS. KORNBAU: Okay. I don't think we have specific examples.

JUDGE SCHEINER: Well, according to -- I'm looking at page 11 of the specification. It's -- there's a prophetic discussion that once you have the amino acid sequence, once you've deduced it from the DNA, then you can synthesize fragments.

MS. KORNBAU: Right.

JUDGE SCHEINER: And that those fragments contain immunoreactive portions attached to sequences designed to provide for some additional property. I'm just looking to see if there is anything in the specification where the technique for detecting one organism versus another is discussed. So far what I'm seeing is pretty generic.

MS. SCALISE: Paragraph 24?

MS. KORNBAU: Excuse me?

MS. SCALISE: Paragraph 24.

MS. KORNBAU: Paragraph 24 was --

JUDGE SCHEINER: Twenty-four? Okay.

MS. KORNBAU: Yeah.

JUDGE SCHEINER: Okay. All right. Let's take a look.

MS. KORNBAU: By growing strains of hemolysin producing fungi in vitro and isolating the hemolysin, it's now possible to use the protein obtained to identify fungi which are isolated from buildings, homes, schools and the like. The fungal strains are grown in a conventional -- but if you're identifying them, it's not saying this is a fungus. It's identifying the specific one.

JUDGE SCHEINER: To me it looks like it's saying you're identifying hemolysin producing fungi, fungi, as a -- it could be interpreted that way, as a group.

MS. KORNBAU: But we interpreted it differently because obviously we're looking for different strains of fungi, or different organisms. Let's put it that way. I don't want to get into the classification.

JUDGE SCHEINER: Right, right. Okay. Well, why don't we move on? We still have a few rejections to --

MS. KORNBAU: Okay. Okay, claims 30 to 32. Oh, for determining if an animal has been exposed to a particular fungus. Okay. The method for determining an animal has been exposed to a particular fungus is contacting the sample with the labeled antibody. One skilled in the art can certainly extrapolate from this method in which the hemolysin has been obtained from the building. I don't see where there's any problem. This is -- the assays themselves are well known in the art. It's -- the whole concept that's important is the fact that we've discovered that there are these markers that can be used to assay for individual specific hemolysin producing organisms. And to put in every little step of the assay I think is insulting to one skilled in the art.

JUDGE SCHEINER: I don't think that's what the Examiner was asking for, but --

JUDGE PRATS: Well, is the distinction actually between what's possessed in the spec, and the Examiner wants it literally laid out word for word? Is that what you're saying?

MS. KORNBAU: That's what I'm saying. I think she's looking for every single little step that one skilled in the art certainly would be able to -- to put in there. I'm not -- I'm a chemist, but I can understand this. I can understand the basic steps of what they're doing, because a lot of these assays are well -- the techniques for the assays are well known in the art. People have been doing immunoassays for what, 40 years? So I think she's looking for more than is necessary. And I think the rejection of 23 to 26 is failing to comply with the written description requirement. They have to be species specific or organism specific, or there would be no point in filing this patent application. We have these markers. The big deal is we found that there are these markers for individual organisms that can be used to determine exposure or presence of.

JUDGE PRATS: Now the -- you're talking about the next to last rejection over claims 23 to 26.

MS. KORNBAU: Mm-hmm.

JUDGE PRATS: It looks like the rationale is pretty much the same as the previous written description over 23 to 26 and 29.

MS. KORNBAU: Mm-hmm.

JUDGE PRATS: Does that sound right?

MS. KORNBAU: That sounds right.

JUDGE PRATS: And it sounds like it's almost the same rejection, just restated.

MS. KORNBAU: Just -- she's worded it differently.

JUDGE PRATS: Yeah.

MS. KORNBAU: I think what she was looking for is the exact wording, and as you know we don't have to have the exact wording. If one skilled in the art can understand that this is what was going on, that's enough. And if a non-immunologist or a non-microbiologist can understand this, one skilled in the art certainly could understand what the inventors had here.

So I think the written description rejections are all about the same, and can be answered basically the same way. We've explained what we're doing, how to do it. One skilled in the art can run these assays with no trouble at all. Once you've tagged the hemolysin with the antibody, it's a fairly straightforward procedure. The invention here was discovering that there are these markers that can be used for such assays.

JUDGE SCHEINER: Were there any rejections that we haven't covered yet?

JUDGE PRATS: There's a 112 second. It was the last rejection, I think.

JUDGE SCHEINER: Oh.

MS. KORNBAU: Oh, because all of the steps for determining if a building contains the hemolysin producing organism -- once again, I think this is so straightforward that one skilled in the art would be able to -- it's -- you obtain a sample. You obtain the hemolysin from the sample. It's very simple to -- we disclose how to obtain the hemolysin from the

sample. You contact it with labeled antibodies to the hemolysin and detect if there is any complex formed. That seems pretty straightforward to me. And I don't think there are any steps missing. I mean, I can certainly -- we've disclosed how to obtain the hemolysin. Again, that's not rocket science. It's something that has been disclosed, one skilled in the art can readily do. Why put all of those little steps into the claim? There might be better ways that someone finds later on, and so it wouldn't be right to restrict the claim to those specific steps of obtaining the hemolysin.

JUDGE SCHEINER: Did you have anything further?

JUDGE MILLS: No. I don't have any questions.

JUDGE SCHEINER: I think we've asked all our questions. If you've -- unless you have anything further, I think we understand the issues.

MS. KORNBAU: No. I just wanted really to answer your questions.

JUDGE SCHEINER: Okay.

MS. KORNBAU: Thank you very much.

JUDGE SCHEINER: All right. Thank you for coming in.

Whereupon, at 9:44 a.m., the proceedings were concluded.